IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
	:	
v.	:	2:17 CR 295 (NBF)
	:	
Andrezj Zielke,	:	
	:	
Defendant.	:	

MOTION TO DISMISS
(WITH CITATION TO AUTHORITY)

COMES NOW Andrezj K. Zielke, MD, the Defendant, by and through counsel, Christopher M. Capozzi, Esquire, pursuant to Rules 12(b)(1) and 47 of the Federal Rules of Criminal Procedure, and submits this *Motion to Dismiss* and states in support thereof as follows*:*

A. Introduction

1. Dr. Zielke is accused in a 121-count indictment of four criminal offenses: *Counts 1 – 112* concern the unlawful distribution of controlled substances in violation of 21 U.S.C. § 841(a)(1) and (b)(1)(C)); *Count 113* concerns conspiracy to unlawfully distribute controlled substances in violation of 21 U.S.C. § 846; *Counts 114 – 117* concern health care fraud in violation of 18 U.S.C. §§ 1347 and 2; and, *Counts 118 – 121* concern money laundering in violation of 18 U.S.C. § 1957. *ECF No. 27* (Superseding Indictment).

2. Each of the offenses alleged depends on the Government's allegation that Dr. Zielke issued prescriptions for Schedule II controlled substances "outside the usual course of professional practice and for no legitimate medical purpose" in violation of 21 U.S.C. § 841. Accordingly, if this either prong of this allegation fails, then entire indictment should be dismissed with prejudice.

3. The Government's assertion of criminal liability is fundamentally flawed and the Indictment should be dismissed with prejudice for three reasons.

a) The Prohibited Acts provision of the Controlled Substance Act (hereafter "CSA") is unconstitutionally vague and ambiguous as applied in this case.

b) The Code of Federal Regulations (hereafter "CFR") does not (in this case) create a basis for imposing criminal liability under Subchapter D of the CSA, in particular 21 U.S.C. § 841 ("Prohibited Acts").

c) The Supreme Court's decision in *United States v. Moore*, 423 U.S. 122 (1975), should be limited to its facts and, therefore, the standard for imposing criminal liability articulated in it should not apply to this case.

4. The standard which the Government has relied on it asserting criminal liability – a prescription issue outside the usual course of practice and for no legitimate purpose – is derived from the *Narcotics Drug Act of December 17, 1914* (38 Stat. 785) ("NDA of 1914"), 21 C.F.R. § 1306.04 and *United States v. Moore*, 423 U.S. 122 (1975).

5. The NDA of 1914 (which applied to the prescription of opiates and heroin for medical purposes) made it a crime "to sell, barter, exchange, or give away any of the narcotic drugs named in the act except in pursuance of a written order" and "to a patient of a registered physician in the course of his professional practice." *See United States v. Behrman*, 258 U.S. 280, 285 (1922).

6. The Code of Federal Regulations provides:

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. . . . . An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04.[1] This section of the CFR was promulgated pursuant to 21 U.S.C. § 821, 829 and 871(b). *See* 36 FR 7799, Apr. 24, 1971, re-designated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005.

7. In *United States v. Moore*, the Supreme Court held that pursuant to 21 U.S.C. § 841 "that registered physicians can be prosecuted under [section] 841 when their activities fall outside the usual course of professional practice." *Moore*, 423 U.S. at 124.[2] The District Court for the Western District of Pennsylvania and the Third Circuit both explained the United States Attorney's Office "must establish . . . the [prescriptions were issued] 'outside the scope of professional practice' and 'not for a legitimate medical purpose.'" *United States v. Rydze*, No. CR 12-262, 2017 WL 1337589, at *1 (W.D. Pa. Apr. 12, 2017)(Conti, J.); *United States v. Maynard*, 278 Fed. Appx. 214, 117-218 (3rd Cir. 2008)(non-precedential opinion); *United States v. Rottschaefer*, 178 Fed. Appx. 145, 146-148 (3rd Cir. 2006)(non-precedential opinion).

A. The Controlled Substances Act, 21 U.S.C. § 841, is unconstitutionally vague and ambiguous as applied in this case.

8. The law at issue in this case – unlawfully dispensing or distributing a controlled substance, specifically doing so outside the usual course of medical practice and for no legitimate

[1] This provision of the CFR further provides:

> (b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
>
> (c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter.

Dr. Zielke is not accused of a violation on the basis of subsections (b) or (c) of 21 C.F.R. § 1306.04.

[2] *Moore* is inapplicable to this case for several reasons, including, but not limited to, that it factually distinct because it concerned dispensing prescriptions for methadone for maintenance purposes by a physician who was not authorized to conduct a methadone maintenance program, among other reasons. *Id.* at 124-126.

purpose – is unconstitutionally vague and ambiguous.[3] First, the CSA itself provides registered physicians with no meaningful guidance as to what constitutes a lawful or unlawful prescription. Second, the Government's approach to determining what is lawful or unlawful conduct which is to outsource the determination to experts who are retained for the purposes of litigation, this approach does not provide physicians with meaningful notice of the legality of their conduct.

9. The Third Circuit recently explained

> A ***statute*** is unconstitutionally vague if ***it*** fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits. [In a] criminal [case], vagueness challenges may be overcome in any specific case where reasonable persons would know their conduct puts them at risk of punishment under the statute.

United States v. Ferriero, 866 F.3d 107, 124 (3d Cir. 2017), cert. denied, 138 S. Ct. 1031, 200 L. Ed. 2d 258 (2018)(internal citations and quotations omitted)(emphasis added). This Court also recently discussed vagueness challenges at length.

---

[3] The Third Circuit has not ruled on whether 21 U.S.C. § 841(a)(1) is not unconstitutionally vague, although several other courts have. *See United States v. Collier, 478 F.2d 268 (5th Cir. 1973)(finding that 21 U.S.C. § 841(a)(1) not vague as applied to physicians); United States v. Robinson, 253 F.Supp.3d 1 (D.D.C. 2017)(same)(citing, United States v. Rosenberg, 515 F.2d 190, 197 (9th Cir.); United States v. Darji, 609 Fed.Appx. 320, 334 (6th Cir. 2015), United States v. Orta–Rosario, 469 Fed.Appx. 140, 143 (4th Cir.); United States v. Brickhouse, No. 3:14-CR-124, 2016 WL 2654359, at *4 (E.D. Tenn. Mar. 30, 2016); United States v. Quinones, 536 F.Supp.2d 267, 274 (E.D.N.Y. 2008); United States v. Birbragher, 576 F.Supp.2d 1000, 1013 (N.D. Iowa 2008), aff'd, 603 F.3d 478 (8th Cir. 2010); United States v. Prejean, 429 F.Supp.2d 782, 805 (E.D. La. 2006).* These cases do not, however, control the outcome in this case. First, none of these cases were authored by the Third Circuit. Second, when it is the intention of a legislature to articulate a specific standard of care it has the knowledge and power to do so. The United States Congress enacted, as it relates to Internet prescribing, 21 U.S.C. § 829(e)(2)(A), which states: "[t]he term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner." The Pennsylvania Legislature enacted 35 P.S. § 780-111(d), relating to professional prescription, which states: A practitioner may prescribe, administer, or dispense a controlled substance or other drug or device only (i) in good faith in the course of his professional practice, (ii) within the scope of the patient relationship, and (iii) in accordance with treatment principles accepted by a responsible segment of the medical profession Third, and perhaps most importantly, none of courts addressed whether the rule articulated in 21 C.F.R. § 1306.04 may be used in the context of determining the reach of 21 U.S.C. § 841. Dr. Zielke specifically contends that the "usual course of practice" and "legitimate purpose" standard may not be used to impose criminal liability because the rule itself is flawed for the reasons discussed in Section A of this *Motion to Dismiss*.

> With respect to the vagueness challenge, the Fifth Amendment provides that "[n]o person shall ... be deprived of life, liberty, or property, without due process of law." U.S. CONST. AMD. V. In the context of criminal prosecutions, it is well established that "a criminal statute must give fair warning of the conduct that it makes a crime." A criminal statute may be deemed void for vagueness if the challenged statute:
>
> > (1) fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits; or (2) authorizes or even encourages arbitrary and discriminatory enforcement. The inquiry is undertaken on a case-by-case basis, and a reviewing court must determine whether the statute is vague as-applied to the affected party.
>
> . . . The party bringing the vagueness challenge bears the burden of demonstrating that the statute is vague as applied to him or her.

United States v. Taylor, 232 F.Supp.3d 741, 754 (W.D.Pa. 2017)(internal citations and quotation marks omitted).

10. A law that "is so indefinite that it 'it encourages arbitrary and erratic arrests and convictions'" is constitutionally infirm. *Colautti v. Franklin*, 439 U.S. 379, 390 (1979)(citations omitted). The most important aspect of the "vagueness doctrine is not actual notice, but . . . the requirement that the ***legislature*** establish minimal guidelines to govern law enforcement." *Smith v. Goguen*, 415 U.S. 566, 574 (1974)(emphasis added). Where the legislature has does not establish standards of law that preclude "policemen, prosecutors and juries [from] pursu[ing] their own personal predilections" there is a denial of due process. *Id.* at 575-576.

11. The statute at issue, 21 U.S.C. § 841(a)(1), does not provide physicians with any meaningful guidance as to what prescribing practices might be unlawful. In fact, the statutory instruction is that a physician's order to dispense or distribute a controlled substance must be "lawful" and the definitions of distribute and dispense also provide no meaningful guidance as to

what prescribing practices might be unlawful.[4] Absolutely nothing within the CSA informs a physician as to what is a lawful or unlawful prescription and a registered physician prescribing a substance which he is registered to prescribe is not on notice that he or she is violating the law by doing so.

12. The Government is not disputing (and likely will not dispute) that Dr. Zielke was (at the time of the allegations in this case) a physician with a current license to practice medicine in the Commonwealth of Pennsylvania and that he held a current Drug Enforcement Administration registration.

13. The Government likely will not dispute that Dr. Zielke had many years of experience as an anesthesiologist, surgeon and in managing chronic and acute pain.

14. The Government is not asserting that Dr. Zielke traded sex for prescriptions; used a sliding fee schedule based on the nature or quantity of medication prescribed; used third-parties to recruit patients for him; or, paid a referral fee in cash or otherwise to third parties for new patients.

15. The Government likely will not dispute that Dr. Zielke:

a) met with each of his patients in person and created a medical record for each one of them;

b) obtained from them a medical history, conducted an in-person physical examination of, and, generally obtained at least one urine specimen from them;

c) on return visits he obtained from, list of current complaints was obtained from, a physical exam was made of, and he met in-person with each of them;

d) required his patients to execute an agreement relating to the acquisition and use of the medication prescribed to them, on occasion called patients in for pill-counts and discharged patients from the practice and on many occasions declined to take on patients;

[4] The term "dispense" means "to deliver a controlled substance to an ultimate user . . . pursuant to a lawful order of a practitioner." *Id.* at § 802(10). The term "distribute" means "to delivery (other than by administering or dispensing) a controlled substance. *Id.* at § 802(11).

e) determined what medications were prescribed, the amounts which were prescribed and the frequency of the prescriptions; and,

f) did not base his fee on the nature or quantity of the medication prescribed.

16. Dr. Zielke is not and will not dispute that he issued the prescriptions at issue in this case.

17. The Government's assertion that selected prescriptions for certain patients were outside the usual course of medical practice and for no legitimate medical purpose is entirely dependent on a review of patient files by retained "experts" for purposes of litigation or possible litigation.[5]

18. In other words, Drs. Thomas and Schwartz, for selected prescriptions for certain patients, disagree with the nature and course of treatment Dr. Zielke recommended and the patient (who had reported the ailment for which treatment was sought) had agreed upon.

19. On the basis of this difference of opinion among professionals (and only this difference of opinion) the Government filed the criminal charges in this case. In other words, to create a prosecutable offense the Government need only search until it finds an expert that will offer an opinion to the effect that "on the basis of the medical record presented to me, the prescription was issued outside the usual course of practice and for no legitimate purpose."

20. A criminal charge based on nothing more than a difference of opinion among experts about the appropriate diagnosis of an ailment, as well as the correct course and scope of treatment, leaves practitioners without meaningful guidance as to whether they may be violating

[5] Dr. Stephen Thomas, one of the Government's experts, was retained by the Government for purposes of this litigation. He opined (on the basis of his review of the medical record alone) that some, but not all of the prescriptions, issued to certain patients were outside the usual course of medical practice and for no legitimate purpose; he did not report examining any of the patients about whom he offered an opinion. Dr. Nathan Schwartz, the Government's other expert, was retained by an insurer for possible litigation. He opined (on the basis of his review of the medical record alone) that certain treatments were unreasonable and unnecessary; he also did not report ever having examining any of the patients about whom he offered an opinion.

the criminal law. This situation by definition leaves policemen, prosecutors and juries free to pursue their own predilections – that is, to find a more agreeable expert or to choose without good reason to believe one expert over another and – and therefore, renders the CSA unconstitutionally vague and ambiguous.

B. The Code of Federal Regulations does not (and cannot) create a basis for imposing criminal liability because the Controlled Substances Act does not authorize the Attorney General to issue regulations pursuant to Subchapter 1, Part D.

21. The Attorney General does ***not*** have authority to promulgate rules and regulations pursuant to *Part D – Offenses and Penalties* of the CSA and the regulation it promulgated is too vague and ambiguous to support a criminal charge.

i. The Attorney General does not have authority to promulgate regulations.

22. The Attorney General has the authority to promulgate rules and regulations pursuant to three specific sections of the CSA. Section 811 of *Part B - Authority to Control Standard and Schedules*, grants the Attorney General has the following authority:

> (a) Rules and regulations of Attorney General; hearing.
>
> The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e), the Attorney General may by rule—
>
> (1) add to such a schedule or transfer between such schedules any drug or other substance if he—
>
> (A) finds that such drug or other substance has a potential for abuse, and
>
> (B) makes with respect to such drug or other substance the findings prescribed by subsection of section 812 of this title for the schedule in which such drug is to be placed; or

> (2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

21 U.S.C. § 811. Section 821 of Part C – *Registration of Manufacturers, Distributors and Dispensers of Controlled Substances*, grants the Attorney General has the following authority:

> The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

21 U.S.C. § 821. Section 871 of Part E - *Part E, Administrative and Enforcement Provisions Registration of Manufacturers*, grants the Attorney General has the following authority:

> (b) Rules and regulations - The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.

21 U.S.C. § 871.

23. Accordingly, the rule at issue – "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" – may not serve the foundation for criminal prosecution under Part D (*Offenses and Penalties*) of Subchapter 1 of the CSA.[6] 21 C.F.R. § 1306.04(a).

ii. *The regulation promulgated is vague and ambiguous*.

24. The "usual course of practice" and "legitimate medical purpose" rule is too amorphous to allow for the imposition of criminal liability for several reasons.

[6] A violation of this particular Federal Regulation may, therefore, only serve as the foundation for a criminal prosecution for a violation of Parts B,C and E of Subchapter 1 of the CSA.

25. First, Congress and the President have not passed a law establishing standard relating to prescriptions issued by registered physicians; or, stating what is in the usual course of practice and what is a legitimate medical purpose. The United States Attorney has instead elected to outsource this determination to the so-called experts it retains well into the criminal investigative process, if not after charges are filed, for purposes of litigation. This is a practice which, if not insane, borders on insanity. The Government – whether intentionally or not – reposes the power to determine whether a crime will be charged in a person who has a financial interest in a prosecution being undertaken. Why not make a magistrate's pay dependent on authorizing the arrest or search warrant and a judge's pay dependent on the conviction of the accused.

26. Second, what guidance relating to the prescription of opioids changes regularly. In fact, the Centers for Disease Control released a letter on April 9, 2019 clarifying the its *Guideline for Prescribing Opioids for Chronic Pain*.[7] Even those guidelines – which were issued on March 16, 2016 – represented a substantial change in the official guidance relating to prescribing opioids.[8] Prior to 2016, physicians looked to the *Federation of State Medical Boards [("FSMB")] Model Policy on the Use of Opioids in the Treatment of Chronic Pain* (July 2013), which the FSMB updated in April 2017 when it published its *Guidelines for the Chronic Use of Opioid Analgesics*.[9] In Pennsylvania, physicians also looked to the *Prescribing Guidelines for Pennsylvania – Treating*

[7] *See* Centers for Disease Control, *Letter from Department of Health and Human Services*, February 28, 2019 (embargoed until April 9, 2019) (https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html).

[8] *See* Centers for Disease Control, *CDC Guidelines for Prescribing Opioids for Chronic Pain* (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html* - Tab: Comparison With Previous Guidelines).

[9] FSMB, *Model Policy on the use of Opioid Analgesics in the Treatment of Chronic Pain* (July 2013) (*https://30qkon2g8eif8wrj03zeh041-wpengine.netdna-ssl.com/wp-content/uploads/2013/10/FSMB-Model-Pain-Policy_July-2013.pdf*); and, FSMB *Guidelines for the Chronic Use of Opioid Analgesics* (April 2017) (*https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf*.)

Chronic Non-Cancer Pain, which were initially approved by the Pennsylvania Medical Board on June 16, 2016 and revised on June 11, 2018.[10] It is essential to remember that none of these guidelines are the law of the land and a physician has an overarching duty to his or her patient to "first do no harm" and a physician who is confronted with new guidance or a change in guidance might be forced to modify or abandon a treatment which is working.

27. Third, state and local governments across the country are seeking to hold "big pharma" liable for misrepresentations to regulators, physicians and patients about the efficacy and safety of their products. *See, e.g*, LoudounNow.Com, *Loudon County File $280M Suit Against Big Pharma*, June 18, 2019 (*https://loudounnow.com/2019/06/18/loudoun-county-files-280m-opioid-suit-against-big-pharma/*); The Guardian, *Johnson & Johnson faces multibillion opioids lawsuit that could upend big pharma*, June 19, 2019 (*https://www.theguardian.com/us-news/2019/jun/22/johnson-and-johnson-opioids-crisis-lawsuit-latest-trial*); NPR, Cities and States Look To Big Pharma To Cover Costs of the Opioid Epidemic, May 27, 2019 (*https://www.npr.org/sections/health-shots/2019/05/27/727319531/cities-and-states-look-to-big-pharma-to-cover-costs-of-the-opioid-epidemic*). In other words, the Government – again whether intentional or not – is prosecuting physicians who reasonably relied the representations of pharmaceutical companies concerning the efficacy and safety of their products, products which the Government itself approved for administration, distribution and dispending for medical purposes.

[10] Pennsylvania Department of State - State Board of Medicine, Board Resources - PA Guidelines (*https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Documents/PA%20Guidelines%20on%20the%20Use%20of%20Opioids%20to%20Treat%20Chronic%20Noncancer%20Pain.pdf*).

28. Accordingly, the "usual course of practice" and "legitimate medical purpose" standard fails to put an ordinary physician on notice of what is or is not criminal conduct and, therefore, cannot serve as a basis for criminal prosecution.

C. The Supreme Court's decision in United States v. Moore should be limited to its facts – that is, it is unlawful for registered physician to prescribe a substance for which he does not possess an authorization.

29. The CSA should not be read, contrary to the broad language used in *United States v. Moore*, to allow the prosecution of any registered physician for distributing or dispensing a controlled substance under 21 U.S.C. § 841; instead, Moore should be limited to allowing the prosecution of a physician who administers, dispenses or distributes outside of the specific bounds his or her DEA registration.

30. The Supreme Court held, in *Moore*, the CSA authorizes the prosecution of "registered physicians . . . under [section] 841 when their activities fall outside the usual course of professional practice." *Moore*, 423 U.S. at 124.

31. In *Moore*, the Supreme Court in interpreting the CSA relied on a standard articulated in the NDA of 1914, "to a patient of a registered physician in the course of his professional practice," and adopted language similar to that used in 21 C.F.R. § 1306.04(a), "usual course of professional practice."

32. However, Congress did not include this language like this within 21 U.S.C. § 841; it did not include like this in the general definitions section of Subpart A of Subchapter 1 of the CSA establishing the meaning of "administering," "dispensing" or "distributing" controlled

substances[11] and it did not authorize the Attorney General to promulgate regulations pursuant to Subpart D of Subchapter 1 of the CSA.

33. Further, in *Moore*, the defendant was dispensing methadone maintenance prescriptions without authorization to conduct a methadone maintenance program. *Id.* at 124-126.

> The indictment covered a 5 ½ month period from late August 1971 to early February 1972. . . .
>
> Methadone is an addictive drug used in the treatment of heroin addicts. If taken without controls it can, like heroin, create euphoric "highs," but if properly administered it eliminates the addict's craving for heroin without providing a "high." The two principal methods of treating heroin addicts with methadone are "detoxification" and maintenance." Under a maintenance program, the addict is given a fixed dose once a day for an indefinite period to keep him from using heroin. . . . Maintenance is the more controversial method of treatment. During the period covered by the indictment, registration under [section] 822, in itself, did not entitle a physician to conduct a maintenance program. **In addition to a [section] 822 registration, the physician who wished to conduct such a program was required to obtain authorization from the Food and Drug Administration for investigation of a new drug. Dr. Moore's authorization by the FDA was revoked in the summer of 1971, and he does not claim that he was conducting an authorized maintenance program**. Instead, his defense at trial was that he had devised a new method of detoxification based on the work of a British practitioner. . . .
>
> **[Dr. Moore] conced[ed] in his brief that he did not observe generally accepted medical practices.**

Id. at 125-126 (emphasis added).

34. A better reading of *Moore* (and one that is more consistent with the statutory scheme) is that it allows the prosecution of physicians who are registered pursuant to 21 U.S.C. §

[11] Although Congress did use "usual course" language in connection with the definitions of "regulated transactions", "online pharmacy," "practice of telephone medicine" and "filling new prescriptions." 21 U.S.C. § 802(39), (52), (54) and (56).

822 (*Persons required to register*) under 21 U.S.C. § 841 when they dispense, distribute or administer[12] outside the specific bounds of their registration.

35. This would allow the prosecution, for example, of a physician who operates a suboxone practice without the requisite suboxone registration; or, a physician who dispenses using a prescription when he or she is only authorized to administer in a hospital setting.

36. Further, there are several critical differences between Dr. Zielke's case and the prosecution brought against Dr. Moore.

a) Dr. Moore was engaged in a "controversial" method of treatment, methadone maintenance.

   Dr. Zielke was not operating a methadone maintenance program; he was involved in a traditional and holistic approach to pain management, which involved examination and interaction with the patient, lifestyle counseling, massage, ozone therapy, platelet rich plasma injections, trigger point injections vitamin supplements, massages and prescribing controlled substances.

b) Although Dr. Moore was a registrant, he was not authorized to operate a methadone maintenance program.

   Dr. Zielke, who was also a registrant, was not prescribing any medications which he did not have the authorization to prescribe.

c) Finally, Dr. Moore conceded he did not observe generally accepted medical practices.

   Dr. Zielke has not and will not make this concession.

37. Accordingly, the Supreme Court's decision in Moore should be limited to its facts – the prosecution of a licensed physician who administers, dispenses or distributes a controlled substance outside of his or her DEA registration.

[12] The term "administer" means "direct application of a controlled substance to the body of a patient . . . by a practitioner." 21 U.S.C. § 802(2). The terms "dispense" and "distribute" are defined above.

WHEREFORE, for the foregoing reasons, the Defendant's Motion to Dismiss should be granted and the Indictment against Dr. Zielke should be dismissed with prejudice.

Respectfully submitted,

/s/ Chris Capozzi

_____

Christopher M. Capozzi (ID # 77162)
100 Ross Street, Suite 340
Pittsburgh, PA 15219
Telephone: 412-471-1648
Facsimile: 412-592-0340
E-mail: chris@cmcapozzilaw.com

CERTIFICATE OF SERVICE

I, Christopher M. Capozzi, hereby certify that on July 19, 2019, a copy of the foregoing was filed electronically with the Clerk of Courts for the United States District Court for the Western District of Pennsylvania.

/s/ Chris Capozzi

_____

Christopher M. Capozzi (ID # 77162)